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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR   | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|------------------------|---------------------|------------------|
| 10/509,249   | 09/28/2004  | Shunichi Kuroda        | 12480-000067/US     | 4499             |
| 36593 7590 02/10/2009<br>HARNESS, DICKEY & PIERCE, P.L.C.<br>P.O. BOX 8910<br>RESTON, VA 20195 |             |                        |                     |                  |
| EXAMINER<br>PENG, BO   |             |                        |                     |                  |
| ART UNIT<br>1648   |             | PAPER NUMBER           |                     |                  |
| MAIL DATE<br>02/10/2009  |             | DELIVERY MODE<br>PAPER |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/509,249

**Applicant(s)**

KURODA ET AL.

**Examiner**

BO PENG

**Art Unit**

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

**DETAILED ACTION**

1. The examiner of your application in the Patent and Trademark Office has been reassigned. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Bo Peng, Art Unit 1648.
2. Upon a review of the prosecution history in this application, the Office has determined that it is necessary to vacate the previous Restriction dated January 8, 2007. A new restriction requirement is necessary as set forth below. The Office regrets any inconvenience this may cause Applicant. A prompt response to *Election/Restrictions* is encouraged by the examiner to expedite the prosecution of this case.
3. Claims 1-28 are pending.

***Election/Restrictions***

4. Restriction is required under 35 U.S.C. 121 and 372.
5. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-16 and 18-27, drawn to a drug that comprises hollow nanoparticles of particle-forming protein, the protein displaying an antibody against a specific cell or tissue and encapsulating a substance to be transferred to the cell for treating a disease.

Group II, claim(s) 17 and 28, drawn to disease treating methods comprising administering the nanoparticle.

6. The inventions listed as Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

7. According to PCT Rule 13.2, unity of invention exists only when the shared or corresponding technical feature is a contribution over the prior art. KURODA (WO 01/64930 A1; PTO-1449, 12/23/04; US 2003/0092069 A1 relied upon as the English equivalent) teaches a transporter of substances, comprising the hollow nanoparticle of particle-forming protein, and a biorecognition molecule, wherein the protein capable of forming a particle is a hepatitis B virus surface antigen protein, wherein the biorecognition molecule is an antibody (see e.g. Claims 1, 5, 6, 9 and 10). Thus, the technical feature is not a contribution over the art and the claims lack unity.

### ***Species Election***

8. This application contains claims directed to more than one species of the generic invention. These species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features. Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

9. If Group I above is elected, Applicant is required to elect following embodiments (1) (2) and (3):

(1) one specific antibody, wherein the antibody is:

- (a) a cancer specific antibody, OR
- (b) an anti-virus protein antibody.

(2) The elected antibody (1) is displayed on the particle by:  
(c) binding to a ZZ tag fused with the particle-forming protein (Claims 3 and 22); OR  
(d) binding to streptavidin or its derivative that is ligated to a streptag fused with the particle (Claims 4 and 23).

- (3) one specific modified hepatic B virus surface antigen (HBsAg), wherein:
- (e) the HBsAg lacks some of amino acids in a pre-S region;
  - (f) the HBsAg retains at least N-terminal amino acids 1-20 of the pre-S region;
  - (g) the HBsAg retains at least N-terminal amino acids 12-31 of the pre-S region;
  - (h) the HBsAg lacks N-terminal amino acids 50-153 of the pre-S region; OR
  - (i) the HBsAg lacks N-terminal amino acids 61-164 of the pre-S region.

10. If Group II above is elected, Applicant is required to elect a disease treating method (4) or (5):

- (4) using the drug of Claim 1; OR
- (5) using the drug of Claim 2.

11. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(A) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common property or activity. According to PCT Rule 13.2 and to the guidelines in Section (f)(i)(B)(I) of Annex B of the PCT Administrative Instructions, all alternatives of a Markush Group must have a common structure. In the present case, the claimed drugs that comprise hollow nanoparticles do not share either a common property/activity, or a common structure. Therefore, these species do not relate to a single general inventive concept under PCT Rule 13.1 and PCT Rule 13.2

12. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37

CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

13. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

14. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

15. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above

policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bo Peng, Ph.D. whose telephone number is 571-272-5542. The examiner can normally be reached on M-F, 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, Ph.D. can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/B. P./  
Examiner, Art Unit 1648